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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|------------------------------|----------------|----------------------|------------------------|-------------------------|--|
| 10/617,976 | 07/11/2003 | Robert M. Scribner | 1759.15100-DIV DIV | 4100 | |
| 26308 7. | 590 09/23/2004 | · | EXAM | EXAMINER | |
| RYAN KROMHOLZ & MANION, S.C. | | | PHILOGEN | PHILOGENE, PEDRO | |
| POST OFFICE BOX 26618 | | | ART UNIT | PAPER NUMBER | |
| MILWAUKEE, WI 53226 | | · | 3732 | | |
| | | 1 | DATE MAILED: 09/23/200 | DATE MAILED: 09/23/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | 1 | | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|------------------|----------|--|--|--|--|
| | Application No. | Applicant(s) | | | | | |
| | 10/617,976 | SCRIBNER ET A | <u>.</u> | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | Pedro Philogene | 3732 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.135(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on 11 Ju | 1) Responsive to communication(s) filed on 11 July 2003. | | | | | | |
| 2a) ☐ This action is FINAL. 2b) ☑ This | | | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition of Claims | | | | | | | |
| 4) Claim(s) 2-28 is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6)⊠ Claim(s) <u>2-28</u> is/are rejected. | | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examine | r. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form P | ΓO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign | priority under 35 U.S.C. § 119(a) |)-(d) or (f). | , | | | | |
| a) All b) Some * c) None of: | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| | | | | | | | |
| Attachment(s) | | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary Paper No(s)/Mail Do | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) Notice of Informal P | | D-152) | | | | |
| Paper No(s)/Mail Date 7/11/03. | 6) Other: | | | | | | |

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,241,734. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that the all the elements of claims 2-28 are to be found in claims 1-21. The difference between claims 2-28 of the application and claims 1-21 of the patent lies in the fact that the patent claims includes many more elements and is thus much more specific. Thus the invention of claims 1-21 is in effect a "species" of the "generic" invention of claims 2-28. It has been held that the generic invention is "anticipated" by the "species". See In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 2-28 are anticipated by claims 1-21 of the patent, they are not patentably distinct from claims 1-21.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholten et al. (5,108,404) in view of Mikhail (5,718,707).

With respect to claim 2, Scholten et al disclose a system for treating a bone having an interior volume occupied, at least in part, by cancellous bone comprising: an access tool (30) sized and configured to establish a percutaneous access path to bone a void forming tool (76) sized and configured to be introduced through the percutaneous access path to form a void, a nozzle; as set forth in column 7, lines 45-47, sized and configured to pass through the percutanous access path and including an interior passage to deliver a filling material into the void; as set forth in column 7, lines 45-68.

It is noted that Scholten et al. did not teach of a an auxiliary tool sized and configured to be received by the interior passage and urge filling material from the nozzle; as claimed by applicant. However, in a similar art, Mikhail evidences the use of an auxiliary tool sized for dispensing and compacting bone graft material into a cavity.

Therefore, given the teaching of Mikhail, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an auxiliary tool in the device of Scholten et al; as taught by Mikhail to dispense and compact bone graft material into the cavity.

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With respect to claims 3-28, the above combination of references teaches all the limitations; as set forth in Scholten et al., column 4, lines 23-68, column 5-8, lines 1-68, column 9, lines 1-31, and as best seen in FIGS. 1-34 of Scholten et al., and as set forth in columns 2-3, lines 1-67, and as best seen in FIGS.1-8 of Mikhail.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

| 5,571,189 | 11-1996 | Kuslich |
|-----------|---------|-------------------|
| 5,788,703 | 08-1998 | Mittelmeier et al |
| 4,338,925 | 07-1982 | Miller |
| 6,248,110 | 06-2001 | Reiley et al. |

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene August 23, 2004

PEDRO PHILOGENE PRIMARY EXAMINER